

Implications of the Legal and Regulatory Environment for Family Planning and Reproductive Health Services Delivery in Ukraine

A Report to the POLICY Project

By

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in collaboration with:
Research Triangle Institute (RTI)
The Centre for Development and Population
Activities (CEDPA)

## **POLICY BRIEF**

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# Acknowledgements

This policy brief was developed with the financial support of the POLICY Project, a project funded by the U.S. Agency for International Development (Contract No. CCP-C-00-95-00023-04). POLICY is implemented by The Futures Group International, Inc., in collaboration with Research Triangle Institute (RTI) and the Centre for Development and Population Activities (CEDPA). Thank you to the USAID Mission in Kyiv for its support for this legal and regulatory (L/R) study.

## Background

In 1995, Ukraine's Cabinet of Ministers adopted the National Family Planning Program (NFPP) for the period 1995-2000. The program calls for widespread provision and promotion of modern contraceptives and reduction in the abortion rate. However, little national financing for the NFPP has been provided since its inception. Despite this lack of funding, great strides have been made. There is now a family planning (FP) center in every oblast in Ukraine, and the types of services available in the centers are expanding.

In March 1999, with POLICY assistance and Ministry of Health (MOH) support, high-level reproductive health (RH) leaders formed a multisectoral RH policy group. The group intends to constitute itself officially in order to foster the development of an RH policy, promote its application throughout Ukraine, and develop the follow-on to the NFPP, which officially concludes in 2000.

As a starting point for collaboration, the multisectoral RH policy group decided to host a roundtable discussion of key RH issues. Dr. Volodymyr Rudiy, a medical doctor and lawyer by training, researched and wrote an inventory of current laws, acts, and regulations relating to population and FP/RH (to be referred to as the L/R inventory). Rudiy laid very important groundwork that allows RH professionals to better target the essential policy issues and delve deeper into selected areas of regulation, and his study provides the basis of this policy brief.

Additional sources of information used to create this policy brief include, but are not limited to, a Social Marketing for Change (SOMARC) Country Assessment on the Women's RH Initiative in Ukraine; a POLICY-supported Key Informant Study conducted in Kyiv by Myroslaw Kohut and Dr. Natalia Lakiza-Sachuk; and a POLICY-supported Client Intercept Study conducted in Odessa, Ukraine.

Building on Rudiy's extensive L/R inventory, this policy brief outlines possible implications of the existing L/R environment for FP/RH service and information delivery in Ukraine. It goes beyond the legal framework to include other critical factors that can have an equally important effect on the availability of contraceptives and provision of FP/RH information and services. This policy brief and the L/R inventory will serve as tools for discussions aimed at improving the RH policy environment in Ukraine.

# Initial Considerations

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# **Initial Considerations**

Access to quality FP/RH services is governed by laws enacted by legislatures and the formal regulations issued by the executive branch to implement the laws. However, access is also affected by a broad range of lower level policies that can have the same or greater impact. Laws and regulations leave enormous discretion for government actions and interpretation, which take the form of executive orders, ministry-level decrees, and service operational policies, standards, and norms. The procedures adopted by the government bureaucracy can also vastly affect the way in which laws are applied; furthermore, health professions, while ultimately regulated by laws, also have wide discretion in adopting their practices. Finally, practices of service providers that may or may not be supported in law are so widely observed that they effectively govern services.

A second consideration that underlies this brief is the role of the private sector (both private voluntary (NGO) and commercial) in the delivery of FP/RH products and services. The less the private sector participates in FP/RH services delivery, the more the costs to the government associated with such services. With the possible exception of one or two small oil producing states, no country in the world appears able to bear the costs of a full range of health care services made accessible to all its population.

#### Purpose

The purpose of this brief is to provide a framework for discussion among senior-level policymakers and program planners of the factors within the L/R environment that may hinder the achievement of their FP/RH service delivery goals. Its aim is to enhance awareness of the wide range of factors within the regulatory environment that can affect FP/RH services delivery; facilitate the identification of those factors that unduly constrain service delivery; encourage discussion of the relative importance of identified constraining factors; and, finally, support the multisectoral RH policy development group's development of a new FP/RH policy and a follow-on to the NFFP.

#### Organization of the Brief

This paper outlines implications of the broadly defined L/R environment in relation to five major FP/RH program areas.

- I. Products/Methods Available
- II. Sources of Supply
- III. Who Can Receive Services and Under What Conditions
- IV. Availability of Information
- V. Program Sustainability

In each section, a brief statement of the implications of laws and the regulatory environment for that area of service delivery is made. Next, selected key regulatory issues related to FP/RH service delivery in the Ukrainian context are presented. Finally, questions related to the key issues that may facilitate discussion and decision making among policymakers are suggested.

#### I. Products/Methods Available

Cross-country experience indicates that the greater the choice of contraceptive methods, the more likely it is that women will find a method with which they are satisfied and use it. A variety of consistently available methods ensure that each woman will be able to find and select a contraceptive method acceptable to her and appropriate for use during each stage of her reproductive life. Many L/R factors can have an impact on the number and range of contraceptive methods available for delivery to FP/RH consumers.

A. Legal Methods. Laws and regulations may prohibit or limit the availability of a product/method within the country.

As clearly stated in the L/R inventory, existing laws and regulations in Ukraine allow for the legal use of a wide range of modern contraceptive methods, such as oral contraceptives, IUDs, condoms, spermicides, injectables, the sponge, abortion, and surgical methods. More than 10 oral contraceptive brand names are legal in Ukraine and there are a large variety of condoms from which to choose.

However, availability of tubal ligation is constrained by stated "medical conditions" for its use. Worldwide experience indicates that no country has reached the level of 60 percent contraceptive prevalence among women in their reproductive years in which tubal ligation is not freely available to all women who request it.

Questions: Do the laws limit the availability of methods? What are the stated medical conditions for tubal ligation? How do they protect the health and well-being of women? Is this type of protection necessary? What are the health risks of tubal ligation compared to the health risks of repeated abortion as a means of limiting family size?

B. Economic Incentives and Outdated Medical Training. Economic incentives and outdated medical training may cause physician providers to limit the otherwise legal contraceptive choices of their clients.

Safe, affordable abortion services within the initial 12 weeks of gestation are guaranteed to all Ukrainian women. According to the SOMARC Country Assessment, fees and "gifts" paid to physician providers, even in the public sector, for abortion services are sufficiently important to many physicians to prevent them from actively encouraging their clients to use other contraceptive methods.

Question: Are there positive or negative incentives that might effect a provider's financial bias toward abortion or one method of FP over another?

C. Lack of updated information or provider bias against certain methods. Hormonal contraceptives, such as injectables and a variety of oral contraceptive formulations are legal and registered for use in Ukraine. Physicians' previous medical training and/or experience with earlier generation hormonal products, however, have reportedly created considerable resistance within the medical profession toward the use of hormonal contraceptives. These providers may not recommend injectable and oral contraceptives to clients, even though their use is medically appropriate, and may not provide adequate support for the continued use of these products by clients. These prescribing behaviors effectively limit the contraceptive choices available to consumers.

Questions: Is there a lack of updated information or a bias among providers against certain methods? What is the content of the medical and nursing school curricula related to hormonal contraceptives? Are there requirements for continuing education for relevant health care workers, such as prescribing physicians, counselors, nurses, midwives, and so forth? If so, do required continuing education courses address current worldwide knowledge and practice related to hormonal contraceptives? Do monitoring or other quality control systems exist that facilitate identification of providers who need additional/updated training?

<u>D. Product Registration.</u> Requirements for product registration before importation and distribution may limit or delay availability of products.

The information required and general procedure for initial registration of drugs in Ukraine appears similar to that of most European and North American countries. Re-registration of drugs, however, is required every five years in Ukraine.

While the law, as summarized in the L/R inventory, states that the government agency responsible for the registration of pharmaceuticals will review each application within 30 days, reports from the commercial sector indicate that registration is often time-consuming and interrupted by bureaucratic delays.

The law, according to the background study, states that the fee for registration of a drug is approximately \$1,000. However, representatives of international pharmaceutical manufacturers working in Ukraine have reported total costs of product registration to range between US\$7,000 and US\$20,000 per product (SOMARC Country Assessment).

Questions: Are there ways to streamline costs and the product registration process? How does the time required for the registration of drugs in Ukraine compare to the time required in other countries? How do the fees required for registration compare to those charged in other countries? How does the commercial sector perceive the time and costs required for product registration—as "normal" for the sector or as unduly burdensome? Under what conditions are "specialized assessments" and "additional examination" of preclinical studies and clinical trials required by the regulatory agency prior to drug registration? How frequently are these additional examinations required? Is re-registration of drugs after five-year intervals necessary? How do the time, effort, and fees required for registration and re-registration of contraceptive products add to their cost once they reach the market?

E. Pricing and Taxation Policies. Pricing and taxation policies can make production, importation, and distribution of contraceptive products financially attractive or unattractive to suppliers. Availability of desirable methods/products will be limited if manufacturers, importers, and distributors perceive that the costs of sales (in both time and money) do not allow a sufficient return on their investment. The cost of taxes will be passed on to the consumer, thus making the products too expensive for the average citizen to afford.

In Ukraine, all imported contraceptive pharmaceutical products are exempt from customs fees (for storage, paperwork and handling). Condoms are not exempt from customs fees; they are subject to a fee of 5-10% of the customs value. Additionally, pharmaceuticals as well as health care services delivered by licensed institutions are exempt from the value-added tax. No contraceptive, according to the L/R inventory, is among those products whose price is controlled by the government. This is very favorable.

Anecdotal reports from commercial sector participants suggest, however, that there are regulatory limitations on the amount of profit that a company or individual is allowed to make in business in Ukraine. Income taxes and taxes on profits are said to be extraordinarily high.

Questions: Are there additional ways to improve pricing and taxation policies? Are condoms exempt from the value-added tax? Are there other taxes or informal fees that must be paid on the importation, distribution, and sales of contraceptive products? How do limitations on allowable profits affect commercial sector interest in promoting important health care products and their sales in Ukraine?

## II. Sources of Supply

Sources of contraceptive supply and FP/RH services are essential elements in access to FP/RH health care. If there are limitations in the number and/or location of outlets, or in the presence of qualified service providers at outlets where health care products and services are available to those who need them, then access to essential goods and services—even when they are not proscribed by law or regulation—are constrained.

FP/RH services may be delivered through the public sector, private voluntary (NGO) sector, or private commercial sector.

A. Public Sector. The public as well as government policymakers and bureaucrats often perceive the public sector as responsible for provision of all health care services—especially preventive health care. These expectations place heavy staff, logistical, and financial burdens on governments, which in many cases throughout the world do not have the resources to meet them.

There is a broad geographic network of public sector outlets for FP/RH care services in Ukraine. Provision of services, such as IUD insertions and contraceptive method prescriptions, however, is limited in public sector outlets to Ob/Gyn specialists; and the types of outlets where these specialist providers work are not always easily available, especially to health care consumers in rural areas.

Questions: What is the most appropriate role for the public sector in the formation of a national RH policy and service/information provision? What is the international experience relevant to IUD insertion, prescribing of oral contraceptives, administering of injectable contraceptives, and the taking of PAP smears by nurses, midwives, physician assistants, and other trained (nonphysician) health care workers? What are the added costs in time, travel, and motivation required of women who wish to use an IUD or other physician-provided contraceptive method but who live in rural areas where there is no nearby Ob/Gyn specialist? What are the medical and/or safety reasons that prevent trained midwives, for example, from routinely inserting IUDs? Are there any efficiencies in costs to the public sector that can be derived from IUD-insertion or similar services delivered by lower levels of trained staff than specialist physicians?

As reported in the L/R inventory, prenatal care and attended deliveries are the right of all women in Ukraine; in addition, there is a network of public sector maternity homes to provide obstetric services. Anecdotally, however, postpartum and postabortion FP/RH counseling is not consistently available at these sites where it would seem most needed and could be most effectively provided.

Questions: What are the advantages/disadvantages of providing FP/RH counseling and service delivery immediately postpartum or postabortion? What, if any, are the staff and logistics conditions that limit the provision of FP/RP counseling at such service delivery sites as maternity homes? What are the administrative and staffing mechanisms required for integration of a broader range of FP/RH services into maternity home care?

Article 49 of the Constitution Ukraine declares that the government shall provide free medical care in state and communal institutions. It does not appear, however, that the government has adequate financial capability to fulfill this obligation; for example, only 0.23 million hryvnyas of the 1.2 million budgeted for national FP programs at the state level in 1998 was provided. Data for local spending were not available for 1998 at the time of the L/R inventory; however, in 1997 less than one-half of the amount budgeted locally for the FP program was provided (1.5 million hryvnyas of 3.5 million planned).

Questions: Can either the state or local governments afford to provide all the FP/RH services necessary for the well being of the population? To whom and/or how should governmental agencies target their available FP/RH and health care resources? From where will FP/RH consumers receive needed services when government resources are not sufficient to meet all demand? What is the role of the private/NGO sector and the private/commercial sector in complementing and/or supplementing the public sector's provision of needed FP/RH services?

<u>B. Private/NGO Sector</u>. The private/NGO sector can provide a channel for delivery of free or low-cost services to segments of the population not served—for geographic, cultural, funding, or other reasons—by the public sector. Typically, the cost of providing such services at low or no price is subsidized by charitable donations from private entities or international donor organizations. Governments may sometimes make some contribution to the operating costs of NGOs, especially when those organizations are providing services or reaching segments of the population that the government cannot or does not reach as successfully and efficiently.

According to the L/R inventory, the role of NGOs in health care on the whole and FP services in particular has been insignificant in Ukraine.

Questions: What is an appropriate role for the NGO sector in the formation of a national RH policy and service/information provision? What is the process for registration and establishing a private/nonprofit organization? Does the time and/or money required for this discourage establishing and operating NGOs? Does the NGO sector possess any financial and/or service delivery advantages in reaching particular segments of the population with needed services? To what extent can the NGO sector provide quality FP/RH services to targeted segments of the population without financial support or technical assistance from the public sector? Does the NGO sector represent any cost efficiencies in service delivery otherwise unavailable to the public sector? Are there specific groups of people within the larger population that might be more receptive to information and services provided by NGOs rather than the public sector?

The Law on Charity and Charity Organizations allows NGO participation in health care delivery, health promotion, health care development, and similar activities. A draft law on the Ukrainian Red Cross, if passed, will provide a well-defined right of that organization to set up hospitals, pharmacies, shelters, and so forth.

Questions: Will separate legislation be required for each NGO that wishes to establish a hospital or provide medical services? Are NGOs allowed to receive funding and other assistance directly from international agencies? Are NGOs allowed to charge a fee for services they deliver to clients, or charge clients for any medical products like contraceptives that they are given?

C. Private/Commercial Sector. The private/commercial sector is a channel for the delivery of FP/RH services to those who can afford to pay for services (or choose to pay in exchange for increased convenience, privacy, or other perceived benefit). Use of the private/commercial sector by those who choose to pay for their FP/RH services lessens the financial burden on the public sector by providing such services to the whole population. Public sector resources can then be used to better serve those segments of the population who cannot afford to pay for what they need. Equity and long-term sustainability of service provision is thus increased.

The private practice of medicine, after receipt of a license, is allowed by law in Ukraine. With almost 13,000 Ob/Gyns in the country, however, only 976 licenses have been granted for private practice in this area.

Questions: What is an appropriate role for the commercial sector in the formation of a national RH policy and service/information provision? What are the fees and other requirements for obtaining a license for the private practice of medicine? How long do physicians who have received such a license report that this process takes? Are there unstated penalties or loss of valuable privileges for physicians who establish private practices? What are the costs in establishing an Ob/Gyn private practice?

According to the L/R inventory, private Ob/Gyn practitioners are not allowed to provide antenatal care, treat complications of pregnancy, carry out surgical interventions, treat STDs, or perform abortions. These are among the top revenue-generating procedures for private practice Ob/Gyn specialists throughout the world, thus making it possible for physicians to sustain their practices outside the framework of the public sector, and in turn allowing clients greater choices.

Questions: Are there ways in which the public sector can work in partnership with the private sector to serve the RH needs of its citizens? What is an appropriate role for the commercial sector in service/information provision? What is the private sector's comparative advantage? Are these services (antenatal care, STD treatment, etc.) provided by private sector practitioners internationally? What are the reasons for eliminating these services from the private practice in Ukraine? What are the possible mechanisms available to ensure the quality of such services delivered in the private sector? How do countries internationally ensure reasonable quality in medical and health care services provided through the private sector?

No law or regulation that seeks to control the fees for service charged by private practice physicians exists. It is, however, reported by physicians operating private practices and clinics that a ceiling on allowable profit has been established by the government. Income and other related taxes are also reported to be quite high. Such constraints on the practitioners' return-on-investment discourage expansion of private sector service delivery.

Questions: What is the advantage of maintaining a ceiling on profit? Does competition for clients among private practice physicians act to reduce prices for similar services offered in the private sector? How do other countries internationally try to ensure affordability of health care services delivered by the private sector? What is the plan for financial sustainability of the NFPP without expanded services delivery by private sector practitioners?

#### III. Who Can Receive Services and Under What Conditions

The delivery of FP/RH services available within a country may be constrained by limitations on potential users who are allowed to receive them. Some of these limitations may be necessary to protect the health and safety of FP/RH clients with special medical needs. Other limitations, however, may unduly restrict access to effective contraceptives or FP/RH services for women and men who need them. Restrictions on who can receive FP/RH services and under what circumstances can be due to age restrictions, requirements for spousal or parental consent, prescription requirements, promulgated standards of practice, and generally held beliefs of service providers.

A. Age Restrictions. Access to contraceptives or other RH services based on a person's age can prevent some—especially sexually active younger people—from receiving these essential services

A woman aged 18 is entitled under the law to receive an abortion or any other FP/RH medical intervention without the consent of her spouse or parents. A woman aged 15 is entitled under the law to receive a prescription for oral contraceptives without parental consent.

Question: Do adolescents have special needs?

B. Rural Population. The regulatory requirement of a physician's prescription for receipt of a contraceptive adds to both the time and costs that a potential contraceptive user must pay in order to obtain the desired product. For some potential contraceptive users, the loss of privacy that occurs with a visit to a health center and the travel, time, and other costs of reaching a physician can become barriers to use. When a prescribing physician is not readily available in his/her geographic area, the potential consumer may lose motivation to obtain and use the product.

Current law and regulation require that all modern contraceptive methods other than condoms be dispensed only with the presentation of a prescription from an Ob/Gyn specialist. This regulation adds to the time and effort "costs" that every woman must "pay" to obtain and use a contraceptive method. In rural areas, the requirement of a prescription written by a specialist physician can mean the need to travel to another, larger town or city in order to have access to such a provider.

Questions: Are there ways to improve access to rural areas? For which contraceptive methods is a prescription required internationally? What are the risks to health for use of each contraceptive method without first having a prescription? How do these risks compare to the risks of pregnancy and/or abortion and to the benefits of contraceptive use? What are the essential screening factors for safe use of each contraceptive method? What types of medical providers can adequately perform/evaluate these essential screening factors? What percentage of the rural population lives in villages not served by an Ob/Gyn specialist?

C. Standards of Medical Practice. The information provided by standards of medical practice, as well as the provider's interpretation of information, can have significant impact on a client's access to any given contraceptive method as well as on the quality of care a client receives. Common medical practice based on an informal consensus among providers, previous training of the provider, or accepted social/cultural norms can often operate with as much authority as written guidelines and standards. When standards of practice are outdated, their implementation creates inefficiencies in treatment and misuse of resources. Inefficiencies in treatment can also discourage clients who need such treatment services from seeking them.

Anecdotal evidence suggests that current treatment practice in Ukraine for STDs includes a 30-day stay in a sanitorium.

Questions: What is the advantage of a 30-day sanitorium stay for treatment of STDs? With modern therapeutics, does such a stay continue to be necessary? How are new treatment guidelines communicated to providers? Is there a mechanism for monitoring physician use of new treatment guidelines?

Under MOH regulations, according to the L/R inventory, all abortions including vacuum aspirations are to be done under anesthesia.

Questions: Is anesthesia for vacuum aspiration general or local? What are the relative risks of general anesthesia compared to the risks of the aspiration procedure? Is anesthesia available for

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all procedures? Are there client-acceptable alternatives to anesthesia for vacuum aspiration procedures?

While Ukrainian law provides HIV/AIDS patients with the right to receive treatment, the L/R inventory does not mention the existence of an order that provides a standard of practice for the medical treatment, care and management of HIV/AIDS. If such an order does not exist then it would be useful to ensure further spread of the disease among caregivers is prevented as well as to ensure that quality of care is provided. Another useful law that has been enacted in other countries provides universally accepted standard precautions for prevention of occupational transmission of HIV infection to health care workers and patients.

Question: Do guidelines for the medical treatment, care and management of HIV/AIDS exist? Do such guidelines need to be developed?

# IV. Availability of Information

Availability of FP and RH-related information has a significant impact on the overall use of these services. Information campaigns can communicate the benefits of FP/RH behaviors, attributes of contraceptive methods, locations at which services are available, correct use of contraceptives, safe-sex practices, brand benefits, and costs of products and services. Information can also allay fears connected with contraceptive use and promote use of contraceptives and other RH practices among selected segments of the population. Constraints on the availability of such information can seriously diminish effective demand for FP and RH services.

There are three categories to which FP/RH-related information can be grouped: information, education, and communication (IEC) programs; sex/family life/RH education in schools; and advertising for both products and service providers.

A. IEC programs. IEC programs use the efficiencies of mass media to communicate important health-related messages to a maximum number of people, with frequent repetition, over a selected period of time. IEC campaigns provide reinforcement of the messages given through personal communication by physicians, nurses, and other trained providers.

A variety of laws and regulations address the responsibility of the government in promoting healthy behaviors, providing information on STD/HIV/AIDS prevention, and informing and educating different categories of the population on issues related to FP and RH. According to the L/R inventory, however, these laws and regulations are not widely implemented primarily because of a lack of government funding for such activities.

Questions: What is the priority standing of public information/education campaigns within the MOH budget? What is the priority standing of the MOH budget within the national budget? Are there avenues available for advocating increased priority for funding for public information/education campaigns? Who are the appropriate audiences for such advocacy? Are there funding alternatives for public information/education campaigns?

B. Education in Schools. Sex/family life/RH education in schools presents an important opportunity to reach young people with essential messages before sexual activity. School curricula also provide insurance that the messages young people receive on these topics is consistent, positive, and correct.

Existing laws provide for the inclusion of FP/RH and STD prevention topics in secondary and higher educational institutions. Lack of funding has reportedly constrained development of the necessary teaching materials; consequently, these topics have not been addressed. Moreover, when FP/RH issues are discussed in mandatory biology classes, anecdotal evidence shows that information on modern methods of contraceptive is often not included.

Questions: Are currently available curricula appropriate? What is the priority standing of sex and FP/RH education in the schools within the MOH budget? Are there avenues available for advocating increased priority for funding for sex and FP/RH education curricula? Who are the appropriate audiences for such advocacy? Are there funding alternatives for FP/RH education in the schools? Can existing curricula be reviewed to ensure inclusion of all necessary topics?

C. Advertising. The ability of pharmaceutical companies to advertise their products and of physicians to advertise their services can provide important information to consumers concerning availability of goods and services, prices, and the benefits of products and services—all at no cost to the public sector. Advertising increases awareness among consumers of important health issues and health behaviors, and can help to correct misinformation and unfounded fears of targeted products (e.g., hormonal contraceptives) among potential consumers. Advertising also helps to generate sufficient business for the private/commercial sector in order that it can remain active in the provision of necessary goods and services within the marketplace.

Existing laws and regulations prohibit the advertising of all medicinal agents that require a physician's prescription. If all contraceptives, with the sole exception of condoms, require a prescription, then no contraceptive products other than condoms can be advertised directly to the public.

Questions: What is an appropriate role for the mass media in providing FP/RH information to the public (particularly with respect to RH rights and responsibilities)? What is the purpose of prohibiting advertising to the consumer for prescription drugs? What is the evolving practice among other countries in regard to the mass media advertisement of prescription drugs? Is increased use of contraceptives important enough to the public health that an exception to the current law and regulation is warranted? What mechanisms exist or can be created to ensure correct information in mass media advertising? Is the government sufficiently well funded to finance all necessary information and promotion of contraceptives and other RH products and services? Do current laws and regulations apply to method-specific (generic) advertising as well as to brand-specific advertising?

## V. Program Sustainability

The long-term sustainability and success of Ukraine's NFPP depends in large part on the availability of sufficient funds to deliver quality FP/RH services to every person who wants and needs them.

Constrained resources, according to the L/R inventory, currently limit the ability of the MOH to fully implement its NFPP. Competing demands on national and state-level budgets appear to be increasing, and many donor agencies are operating under similar funding constraints.

Questions: What roles can the private/NGO and private/commercial sectors play in complementing and supplementing the public sector's provision of essential services in FP and RH? Can provision of FP/RH services through private/NGO and private/commercial sector channels alleviate any of the funding pressure now experienced by the public sector? If so, how

can the private/NGO and private/commercial sectors be encourage to expand their participation in FP/RH services delivery?

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